4. SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

SPONSOR:

Medivision (U.S.A.), Inc.
1301 Goshen Parkway
West Chester, PA 19380

Contact: Sandra Williamson

DEVICE NAME: Medivision IGS system

COMMON OR USUAL NAME Image Guided Surgery System

DEVICE CLASSIFICATION: Class II
21 CFR 882.4560, Sterotaxic Instrument

PREDICATE DEVICE:

K954276, StealthStation
K990214, StealthStation System with FluoroNav Module
K992461, StealthStation System Treatment Guidance Platform

DEVICE DESCRIPTION: The Medivision IGS system serves as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The system provides the surgeon with real-time surgical instrument location information in relation to patient preoperative or intraoperative diagnostic images.

The Medivision IGS system is comprised of a computer workstation, a camera unit, infrared light emitting diode (LED) shields attached to the system tools, and a tool interface box. The camera unit detects the LEDs on the tools and transmits location data to the computer. The data is transformed by proprietary software to show real-time location of instruments in relation to CT, MRI, or fluoroscopic patient images. The Medivision IGS system can identify up to 12 tools at one time.

INTENDED USE: The Medivision IGS system is intended as a surgical aid for precisely locating anatomical structures in either open or percutaneous procedures. The Medivision IGS system is indicated for any medical condition where reference to a rigid anatomical structure, such as the spine or bones of the extremities, can be identified relative to a CT- or MR-based model or fluoroscopy images of the anatomy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 7 2001

Ms. Sandra Williamson
Regulatory Consultant
Medivision (U.S.A.), Inc.
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K003699
Trade Name: Medivision IGS System
Regulatory Class: II
Product Code: HAW
Dated: November 27, 2000
Received: December 1, 2000

Dear Ms. Williamson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K003699

Device Name: Medivision IGS system

INDICATIONS/CONTRAINDICATIONS:

The Medivision IGS system is intended as a surgical aid for precisely locating anatomical structures in either open or percutaneous procedures. The Medivision IGS system is indicated for any medical condition where reference to a rigid anatomical structure, such as the spine or bones of the extremities, can be identified relative to a CT- or MR-based model or fluoroscopy images of the anatomy.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003699